

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

CYNTHIA THIBAUT AND ROBERT  
DEROSTYNE,

Plaintiffs,

v.

MERCK & CO., INC. and NOVARTIS  
PHARMACEUTICALS CORPORATION,

Defendants.

Civil Action No.: 1:08-cv-05544

**ANSWER AND DEFENSES OF  
DEFENDANT NOVARTIS  
PHARMACEUTICALS  
CORPORATION TO PLAINTIFFS'  
COMPLAINT**

**JURY DEMAND**

Defendant Novartis Pharmaceuticals Corporation (“NPC”), by and through its counsel, responds to plaintiffs’ Complaint and Jury Demand (“the Complaint”) as follows:

1. Paragraph 1 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint and therefore denies the same.

2. Paragraph 2 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 2 of the Complaint and therefore denies the same.

3. Paragraph 3 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 3 of the Complaint and therefore denies the same.

4. Paragraph 4 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 4 of the Complaint and therefore denies the same.

5. Paragraph 5 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 5 of the Complaint and therefore denies the same.

6. Paragraph 6 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 6 of the Complaint and therefore denies the same.

7. Paragraph 7 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 7 of the Complaint and therefore denies the same.

8. Paragraph 8 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 8 of the Complaint and therefore denies the same.

9. Paragraph 9 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks

sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 9 of the Complaint and therefore denies the same.

10. Paragraph 10 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 10 of the Complaint and therefore denies the same.

11. Paragraph 11 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 11 of the Complaint and therefore denies the same.

12. Paragraph 12 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 12 of the Complaint and therefore denies the same.

13. Paragraph 13 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 13 of the Complaint and therefore denies the same.

14. In response to the allegations in the first sentence in Paragraph 14 of the Complaint, NPC admits that it is a corporation incorporated under the laws of the state of Delaware with its principal offices located in East Hanover, New Jersey. NPC lacks sufficient knowledge or information to determine what time periods plaintiffs assert are “at all relevant times herein” in the second sentence in Paragraph 14 of the Complaint and therefore NPC is

unable to respond to the allegations contained therein. To the extent that a response is required, NPC admits that it promotes and distributes Zometa<sup>®</sup>. NPC denies the remaining allegations in Paragraph 14 of the Complaint.

15. In response to the allegations in Paragraph 15 of the Complaint, NPC lacks sufficient knowledge or information to determine what time periods plaintiffs assert are “[a]t all relevant times hereto” and therefore NPC is unable to respond to the allegations contained therein. To the extent that a response is required, NPC admits that it markets, promotes, and sells Zometa<sup>®</sup> in all fifty states in the United States, including Virginia. NPC denies the remaining allegations in Paragraph 15 of the Complaint.

16. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 16 of the Complaint and therefore denies the same.

17. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 17 of the Complaint and therefore denies the same.

18. NPC lacks sufficient knowledge or information to determine what time periods plaintiffs assert are “at all relevant times ” in Paragraph 18 of the Complaint and therefore NPC is unable to respond to the allegations contained therein. To the extent that a response is required, NPC admits that it does business in all fifty states in the United States, including Virginia. NPC denies the remaining allegations in Paragraph 18 of the Complaint.

19. NPC lacks sufficient knowledge or information to determine what time periods plaintiffs assert are “at all relevant times ” in Paragraph 19 of the Complaint and therefore NPC is unable to respond to the allegations contained therein. Further, NPC does not know the meaning that plaintiffs ascribe to the phrase “agents, servants, employees and apparent agents” and therefore is unable to respond to the allegations contained therein and denies the same. To

the extent that a response is required, NPC admits that it markets, distributes and sells Zometa<sup>®</sup>. NPC admits that Zometa<sup>®</sup> is a bisphosphonic acid. NPC affirmatively avers that Zometa<sup>®</sup> is approved by the Food and Drug Administration (“FDA”) for the indications listed on the product’s label. NPC denies the allegations in Paragraph 19 of the Complaint to the extent that they mischaracterize or misstate information contained on the label for Zometa<sup>®</sup>. NPC denies the remaining allegations in Paragraph 19 of the Complaint.

20. NPC lacks sufficient knowledge or information to determine what time periods plaintiffs assert are “at all relevant times ” in Paragraph 20 of the Complaint and therefore NPC is unable to respond to the allegations contained therein. Further, NPC does not know the meaning that plaintiffs ascribe to the phrase “agents, apparent agents, servants or employees” and therefore is unable to respond to the allegations contained therein and denies the same. To the extent that a response is required, NPC admits that it sells and distributes Zometa<sup>®</sup> in all fifty states in the United States, including Virginia. NPC denies the remaining allegations in Paragraph 20 of the Complaint.

21. NPC does not know the meaning that plaintiffs ascribe to the phrase “derives substantial revenue” in Paragraph 21 of the Complaint and therefore is unable to respond to the allegations contained therein and denies the same. To the extent that a response is required, NPC admits that it sells and distributes Zometa<sup>®</sup> in all fifty states in the United States, including Virginia. NPC admits that it obtains profit from its sale of products in the United States, including in Virginia. NPC denies any remaining allegations in Paragraph 21 of the Complaint.

22. The allegations contained in Paragraph 22 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 22 of the Complaint.

23. In response to the allegations in the first sentence in Paragraph 23 of the Complaint, NPC admits that it sells and distributes Zometa<sup>®</sup> in all fifty states in the United States, including Virginia. NPC denies the remaining allegations in the first sentence in Paragraph 23 of the Complaint. The allegations in the second sentence in Paragraph 23 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in the second sentence in Paragraph 23 of the Complaint. NPC denies any remaining allegations in Paragraph 23 of the Complaint.

24. NPC does not know the meaning that plaintiffs ascribe to the phrase “agents, servants, employees and apparent agents” and therefore is unable to respond to the allegations contained therein and denies the same. To the extent that a response is required, NPC admits that it distributes and sells Zometa<sup>®</sup>. NPC admits that Zometa<sup>®</sup> is approved by the Food and Drug Administration (“FDA”) for the indications listed on its label. NPC denies the allegations in Paragraph 24 of the Complaint to the extent that they mischaracterize or misstate information contained on the label for Zometa<sup>®</sup>. NPC admits that it is aware that the law permits doctors to prescribe medications for off-label uses. NPC specifically denies promoting Zometa<sup>®</sup> for off-label uses. NPC denies all remaining allegations in Paragraph 24 of the Complaint.

25. The allegations in Paragraph 25 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 25 of the Complaint. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa<sup>®</sup>.

26. The allegations in Paragraph 26 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 26 of the Complaint.

27. The allegations in Paragraph 27 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 27 of the Complaint.

28. NPC lacks sufficient knowledge or information to determine whether plaintiff was treated with Zometa<sup>®</sup> and whether plaintiff suffered any injury and therefore denies the same. The remaining allegations in Paragraph 28 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 28 of the Complaint. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa<sup>®</sup>. NPC also specifically denies that plaintiffs are entitled to any of relief sought in Paragraph 28 of the Complaint. In particular, NPC denies that plaintiffs are entitled to punitive damages.

29. The allegations in Paragraph 29 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 29 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 29 of the Complaint and therefore denies the same.

30. The allegations in Paragraph 30 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 30 of the Complaint and therefore denies the same.

31. The allegations in Paragraph 31 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 31 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response

is required, NPC admits that it does business in New York. NPC lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 31 of the Complaint and therefore denies the same.

32. Paragraph 32 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 32 of the Complaint and therefore denies the same.

33. NPC lacks sufficient knowledge or information to determine what time periods plaintiffs assert are “[a]t all relevant times herein” in Paragraph 33 of the Complaint and therefore NPC is unable to respond to the allegations contained therein. To the extent that a response is required, NPC admits that it markets, distributes, and sells Zometa<sup>®</sup>. NPC denies the remaining allegations in Paragraph 33 of the Complaint.

34. Paragraph 34 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC admits that Zometa<sup>®</sup> is a bisphosphonic acid. NPC refers the Court to the information contained on the labeling for Fosamax<sup>®</sup>, and denies any allegations in Paragraph 34 of the Complaint to the extent that they mischaracterize or misstate that labeling information. NPC denies any remaining allegations in Paragraph 34 of the Complaint.

35. Paragraph 35 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC admits that some bisphosphonates contain nitrogen and some do not and that Aredia<sup>®</sup> and Zometa<sup>®</sup> are bisphosphonic acids that contain a nitrogen atom. NPC refers the Court to the PDR for Fosamax<sup>®</sup> for its actual language and full text. NPC also refers the Court to the information



contained on the labeling for Fosamax<sup>®</sup>, Zometa<sup>®</sup>, Aredia<sup>®</sup>, Bondronat<sup>®</sup>, Didronel<sup>®</sup>, Bonefos<sup>®</sup>, Loron<sup>®</sup>, and Skelid<sup>®</sup>, and denies any allegations in Paragraph 35 of the Complaint to the extent that they mischaracterize or misstate that labeling information. NPC denies any remaining allegations in Paragraph 35 of the Complaint.

36. NPC denies the allegations in Paragraph 36 of the Complaint.

37. NPC denies the allegations contained in Paragraph 37 of the Complaint.

38. Paragraph 38 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC admits that the FDA drafted an “ODS Postmarketing Safety Review,” dated August 25, 2004, but avers that the document speaks for itself. NPC denies the allegations in Paragraph 38 of the Complaint to the extent that they mischaracterize or misstate that document and/or its contents. NPC denies any remaining allegations in Paragraph 38 of the Complaint.

39. Paragraph 39 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC affirmatively avers that the “ODS Postmarketing Safety Review” dated August 25, 2004 speaks for itself. NPC denies the allegations in Paragraph 39 of the Complaint because they mischaracterize or misstate that document and/or its contents.

40. The allegations in Paragraph 40 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 40 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 40 of the complaint.

41. Paragraph 41 of the Complaint contains allegations regarding parties other than NPC to which no response is required. The allegations in the first clause in the first sentence in

Paragraph 41 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained therein. NPC lacks sufficient knowledge or information to determine whether plaintiff was treated with Zometa<sup>®</sup> and whether plaintiff was injured and therefore denies the same. NPC lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 48 of the Complaint and therefore denies the same. NPC specifically denies that any of the injuries alleged in the Complaint were caused by Zometa<sup>®</sup>.

42. The allegations in Paragraph 42 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 42 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 42 of the complaint. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa<sup>®</sup>.

43. The allegations in Paragraph 43 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 43 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 43 of the complaint. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa<sup>®</sup>.

44. The allegations in Paragraph 44 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 44 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 44 of the Complaint and therefore denies the same.

45. The allegations in Paragraph 45 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 45 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 45 of the Complaint.

46. The allegations in Paragraph 46 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 46 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 46 of the complaint.

47. The allegations in Paragraph 47 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 47 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 47 of the complaint.

48. The allegations in Paragraph 48 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 48 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 48 of the complaint. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa<sup>®</sup>.

49. In response to Paragraph 49 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

50. The allegations in Paragraph 50 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 50 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC admits that applicable law imposes certain duties upon manufacturers and

distributors of products, but denies that Paragraph 50 of the Complaint accurately sets forth those duties. NPC denies the remaining allegations in Paragraph 50 of the Complaint.

51. The allegations in Paragraph 51 of the Complaint and its subparts (a) through (f) constitute legal conclusions to which no response is required. Further, Paragraph 51 of the Complaint and its subparts (a) through (f) contain allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 51 of the Complaint and its subparts (a) through (f).

52. Paragraph 52 of the Complaint contains allegations regarding parties other than NPC to which no response is required. Further, the allegations in the first clause in the first sentence in Paragraph 52 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained therein. NPC lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 52 of the Complaint and therefore denies the same. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa<sup>®</sup>.

53. The allegations in Paragraph 53 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 53 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 53 of the complaint.

54. The allegations in Paragraph 54 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 54 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 54 of the complaint. NPC specifically

denies that any injuries alleged in the Complaint were caused by Zometa<sup>®</sup>. NPC also specifically denies that plaintiffs are entitled to any of the relief sought in Paragraph 54 of the Complaint.

55. The allegations in Paragraph 55 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 55 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 55 of the Complaint. NPC specifically denies that plaintiffs are entitled to any of the relief sought in Paragraph 55 of the Complaint.

With respect to the allegations in the unnumbered paragraph following Paragraph 55 of the Complaint, which begin with the word “WHEREFORE,” these allegations constitute legal conclusions to which no response is required. Further, the unnumbered paragraph following Paragraph 55 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies that plaintiffs are entitled to any of the relief requested therein. In particular, NPC denies that plaintiffs are entitled to punitive damages.

56. In response to Paragraph 56 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

57. The allegations in Paragraph 57 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 57 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 57 of the complaint. NPC specifically denies that Zometa<sup>®</sup> is “defective” and/or “unreasonably dangerous.”

58. Paragraph 58 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required and in response

to the allegations in the first clause in Paragraph 58 of the Complaint, NPC admits that it sells, distributes, supplies, markets, and promotes Zometa<sup>®</sup>. NPC denies the remaining allegations in the first clause in Paragraph 58 of the Complaint. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in the second clause in Paragraph 58 of the Complaint and therefore denies the same. NPC denies any remaining allegations in Paragraph 58 of the Complaint.

59. Paragraph 59 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 59 of the Complaint and therefore denies the same.

60. The allegations in Paragraph 60 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 60 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 60 of the Complaint.

61. The allegations in Paragraph 61 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 61 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 61 of the Complaint. NPC specifically denies that Zometa<sup>®</sup> is “defective” and/or “unreasonably dangerous.”

62. The allegations in Paragraph 62 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 62 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response

is required, NPC denies the allegations in Paragraph 62 of the Complaint. NPC specifically denies that Zometa<sup>®</sup> is “defective.”

63. The allegations in Paragraph 63 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 63 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 63 of the Complaint. NPC specifically denies that Zometa<sup>®</sup> is “defective” and/or “unreasonably dangerous.”

64. Paragraph 64 of the Complaint contains allegations regarding parties other than NPC to which no response is required. Further, the allegations in the first clause in the first sentence in Paragraph 64 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in the first clause in the first sentence in Paragraph 64 of the Complaint. In response to the allegations in the second clause in the first sentence in Paragraph 64 of the Complaint, NPC admits that it markets and sells Zometa<sup>®</sup>. NPC denies the remaining allegations in the second clause in the first sentence in Paragraph 64 of the Complaint. The allegations in the second sentence in Paragraph 64 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in the second sentence in Paragraph 64 of the Complaint. NPC denies any remaining allegations in Paragraph 64 of the Complaint.

65. The allegations in Paragraph 65 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 65 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 65 of the Complaint.

66. Paragraph 66 of the Complaint contains allegations regarding parties other than NPC to which no response is required. Further, the allegations in the first clause in the first sentence in Paragraph 66 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained therein. NPC lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 66 of the Complaint and therefore denies the same. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa<sup>®</sup>.

67. The allegations in Paragraph 67 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 67 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 67 of the Complaint.

68. The allegations in Paragraph 68 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 68 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 68 of the complaint. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa<sup>®</sup>. NPC also specifically denies that plaintiffs are entitled to any of the relief sought in Paragraph 68 of the Complaint.

69. The allegations in Paragraph 69 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 69 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 69 of the Complaint. NPC specifically denies that plaintiffs are entitled to any of the relief sought in Paragraph 69 of the Complaint.



With respect to the allegations in the unnumbered paragraph following Paragraph 69 of the Complaint, which begin with the word “WHEREFORE,” these allegations constitute legal conclusions to which no response is required. Further, the unnumbered paragraph following Paragraph 69 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies that plaintiffs are entitled to any of the relief requested therein. In particular, NPC denies that plaintiffs are entitled to punitive damages.

70. In response to Paragraph 70 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

71. The allegations in Paragraph 71 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 71 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 71 of the Complaint.

72. The first sentence in Paragraph 72 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations contained therein and therefore denies the same. The allegations in the second sentence in Paragraph 72 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in the second sentence in Paragraph 72 of the Complaint.

73. The allegations in Paragraph 73 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 73 of the Complaint contains allegations

regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 73 of the Complaint.

74. The allegations in Paragraph 74 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 74 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 74 of the Complaint and therefore denies the same.

75. Paragraph 75 of the Complaint contains allegations regarding parties other than NPC to which no response is required. Further, the allegations in the first clause in the first sentence in Paragraph 75 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained therein. NPC lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 75 of the Complaint and therefore denies the same. NPC specifically denies that any of the injuries alleged in the Complaint were caused by Zometa<sup>®</sup>.

76. The allegations in Paragraph 76 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 76 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 76 of the Complaint.

77. The allegations in Paragraph 77 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 77 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 77 of the complaint. NPC specifically denies that any of the injuries alleged in the Complaint were caused by Zometa<sup>®</sup>. NPC also

specifically denies that plaintiffs are entitled to any of the relief sought in Paragraph 77 of the Complaint.

78. The allegations in Paragraph 78 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 78 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 78 of the Complaint. NPC specifically denies that plaintiffs are entitled to any of the relief sought in Paragraph 78 of the Complaint.

With respect to the allegations in the unnumbered paragraph following Paragraph 78 of the Complaint, which begin with the word “WHEREFORE,” these allegations constitute legal conclusions to which no response is required. Further, the unnumbered paragraph following Paragraph 78 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies that plaintiffs are entitled to any of the relief requested therein. In particular, NPC denies that plaintiffs are entitled to punitive damages.

79. In response to Paragraph 79 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

80. The first sentence in Paragraph 72 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations contained therein and therefore denies the same. NPC does not know what time periods plaintiffs assert in the second sentence in Paragraph 80 of the Complaint and therefore NPC is unable to respond. To the extent that a response is required, NPC admits that it

distributes, promotes, and sells Zometa<sup>®</sup>. NPC denies the remaining allegations in the second sentence in Paragraph 80 of the Complaint.

81. The first sentence in Paragraph 81 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations contained therein and therefore denies the same. The allegations in the second sentence in Paragraph 81 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in the second sentence in Paragraph 81 of the Complaint.

82. NPC lacks sufficient knowledge or information to determine what time periods plaintiffs assert in Paragraph 82 of the Complaint and therefore is unable to respond to the allegations asserted therein. Further, Paragraph 82 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC admits that it is aware that doctors can prescribe Zometa<sup>®</sup> for the indications listed on its label. Further, NPC admits that it is aware that the law permits doctors to prescribe medications for off-label uses. NPC denies any remaining allegations in Paragraph 82 of the Complaint.

83. The allegations in Paragraph 83 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 83 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 83 of the Complaint and therefore denies the same.

84. The allegations in Paragraph 84 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 84 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 84 of the Complaint.

85. The allegations in Paragraph 85 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 85 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 85 of the Complaint and therefore denies the same.

86. The allegations in Paragraph 86 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 86 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations contained therein and therefore denies the same.

87. Paragraph 87 of the Complaint contains allegations regarding parties other than NPC to which no response is required. Further, the allegations in the first clause in the first sentence in Paragraph 87 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained therein. NPC lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 87 of the Complaint and therefore denies the same. NPC specifically denies that any of the injuries alleged in the Complaint were caused by Zometa<sup>®</sup>.

88. The allegations in Paragraph 88 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 88 of the Complaint contains allegations

regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 88 of the Complaint.

89. The allegations in Paragraph 89 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 89 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 89 of the complaint. NPC specifically denies that any of the injuries alleged in the Complaint were caused by Zometa<sup>®</sup>. NPC also specifically denies that plaintiffs are entitled to any of the relief sought in Paragraph 89 of the Complaint.

90. The allegations in Paragraph 90 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 90 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 90 of the Complaint. NPC specifically denies that plaintiffs are entitled to any of the relief sought in Paragraph 90 of the Complaint.

With respect to the allegations in the unnumbered paragraph following Paragraph 90 of the Complaint, which begin with the word “WHEREFORE,” these allegations constitute legal conclusions to which no response is required. Further, the unnumbered paragraph following Paragraph 90 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies that plaintiffs are entitled to any of the relief requested therein. In particular, NPC denies that plaintiffs are entitled to punitive damages.

91. In response to Paragraph 91 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

92. Paragraph 92 of the Complaint and its subparts (a) and (b) contain allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 92 of the Complaint and its subparts (a) and (b) and therefore denies the same.

93. Paragraph 93 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 93 of the Complaint and therefore denies the same.

94. Paragraph 94 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 94 of the Complaint and therefore denies the same.

95. Paragraph 95 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 95 of the Complaint and therefore denies the same.

96. Paragraph 96 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 96 of the Complaint and therefore denies the same.

97. Paragraph 97 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks

sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 97 of the Complaint and therefore denies the same.

98. Paragraph 98 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 98 of the Complaint and therefore denies the same.

99. Paragraph 99 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 99 of the Complaint and therefore denies the same.

100. Paragraph 100 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 100 of the Complaint and therefore denies the same.

101. The allegations in Paragraph 101 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 101 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 101 of the Complaint. NPC specifically denies that plaintiffs are entitled to any of the relief sought in Paragraph 101 of the Complaint.

The unnumbered paragraph following Paragraph 101 of the Complaint, which begins with the word “WHEREFORE,” contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient



knowledge or information to form a belief as to the truth of the allegations in the unnumbered paragraph following Paragraph 101 of the Complaint and therefore denies the same.

102. In response to Paragraph 102 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

103. The allegations in Paragraph 103 of the Complaint and its subparts (a) and (b) constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 103 of the Complaint and its subparts (a) and (b).

104. The allegations in Paragraph 104 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 104 of the Complaint.

105. The allegations in Paragraph 105 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 105 of the Complaint.

106. The allegations in Paragraph 106 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 106 of the Complaint.

107. The allegations in Paragraph 107 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 107 of the Complaint and therefore denies the same.

108. The allegations in Paragraph 108 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained in Paragraph 108 of the Complaint.

109. The allegations in the first clause in the first sentence in Paragraph 109 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained therein. NPC lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 109 of the Complaint and therefore denies the same. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa<sup>®</sup>.

110. The allegations in Paragraph 110 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 110 of the Complaint.

111. The allegations in Paragraph 111 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 111 of the complaint. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa<sup>®</sup>. NPC also specifically denies that plaintiffs are entitled to any of the relief sought in Paragraph 111 of the Complaint.

112. The allegations in Paragraph 112 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 112 of the Complaint. NPC specifically denies that plaintiffs are entitled to any of the relief sought in Paragraph 112 of the Complaint.

With respect to the allegations in the unnumbered paragraph following Paragraph 112 of the Complaint, which begin with the word “WHEREFORE,” these allegations constitute legal

conclusions to which no response is required. To the extent that a response is required, NPC denies that plaintiffs are entitled to any of the relief requested therein. In particular, NPC denies that plaintiffs are entitled to punitive damages.

113. In response to Paragraph 113 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

114. Paragraph 114 of the Complaint and its subparts (a) and (b) contain allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 114 of the Complaint and its subparts (a) and (b) and therefore denies the same.

115. Paragraph 115 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 115 of the Complaint and therefore denies the same.

116. Paragraph 116 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 116 of the Complaint and therefore denies the same.

117. Paragraph 117 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 117 of the Complaint and therefore denies the same.

118. Paragraph 118 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 118 of the Complaint and therefore denies the same.

119. Paragraph 119 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 119 of the Complaint and therefore denies the same.

120. Paragraph 120 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 120 of the Complaint and therefore denies the same.

121. Paragraph 121 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 121 of the Complaint and therefore denies the same.

122. The allegations in Paragraph 122 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 122 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 122 of the Complaint. NPC specifically denies that plaintiffs are entitled to any of the relief sought in Paragraph 122 of the Complaint.

The unnumbered paragraph following Paragraph 122 of the Complaint, which begins with the word “WHEREFORE,” contains allegations regarding parties other than NPC to which

no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in the unnumbered paragraph following Paragraph 122 of the Complaint and therefore denies the same.

123. In response to Paragraph 123 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

124. The allegations in Paragraph 124 of the Complaint and its subparts (a) and (b) constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 124 of the Complaint and its subparts (a) and (b).

125. The allegations in Paragraph 125 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 125 of the Complaint.

126. The allegations in Paragraph 126 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 126 of the Complaint.

127. The allegations in Paragraph 127 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 127 of the Complaint.

128. The allegations in Paragraph 128 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 128 of the Complaint regarding plaintiffs' alleged reliance and therefore denies the same. NPC denies all remaining allegations in Paragraph 128 of the Complaint.

129. The allegations in the first clause in the first sentence in Paragraph 129 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained therein. NPC lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 129 of the Complaint and therefore denies the same. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa<sup>®</sup>.

130. The allegations in Paragraph 130 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 130 of the Complaint.

131. The allegations in Paragraph 131 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 131 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 131 of the Complaint. NPC specifically denies that plaintiffs are entitled to any of the relief sought in Paragraph 131 of the Complaint.

132. The allegations in Paragraph 132 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 132 of the Complaint. NPC specifically denies that any injuries alleged in the Complaint were caused by Zometa<sup>®</sup>. NPC also specifically denies that plaintiffs are entitled to any of the relief sought in Paragraph 132 of the Complaint.

With respect to the allegations in the unnumbered paragraph following Paragraph 132 of the Complaint, which begin with the word “WHEREFORE,” these allegations constitute legal conclusions to which no response is required. To the extent that a response is required, NPC

denies that plaintiffs are entitled to any of the relief requested therein. In particular, NPC denies that plaintiffs are entitled to punitive damages.

133. Every allegation in the Complaint that is not specifically and expressly admitted in this Answer is hereby specifically and expressly denied.

### **AFFIRMATIVE DEFENSES**

1. The Complaint, in whole or part, fails to state a claim or cause of action against NPC upon which relief can be granted.

2. All claims against defendants other than Novartis Pharmaceuticals Corporation are improperly joined or fraudulently joined in this action.

3. Venue is inconvenient to the parties in the United States District Court for the Southern District of New York, and this matter should be transferred to an appropriate jurisdiction.

4. The doctrines contained in Restatement (Second) of Torts § 402A, Comment K, bar plaintiffs' claims against NPC in whole or in part.

5. The doctrine(s) contained in Restatement (Third) of Torts, Product Liability §§ 4 and 6, bar plaintiffs' claims against NPC in whole or in part.

6. Applicable statutes of limitations or repose bar plaintiffs' claims in whole or in part.

7. Plaintiffs' misuse or abnormal use of the product or failure to follow instructions bar the plaintiffs' claims in whole or in part.

8. The alleged injuries to plaintiffs were proximately caused by the misuse, abuse, alteration, and/or failure to properly utilize, maintain, or care for the product by persons other than NPC.

9. If plaintiffs' used a product sold by NPC, then plaintiffs' claims are barred, in whole or in part, because plaintiffs assumed the risks disclosed by the product labeling, by the prescribing physicians, or by other persons or entities.

10. Any alleged negligent or culpable conduct of NPC, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of plaintiffs' alleged injuries.

11. If plaintiffs used a product sold by NPC, plaintiffs used the product for "off-label" purposes, which bars the plaintiffs' claims.

12. The "learned intermediary" doctrine bars plaintiffs' claims.

13. Plaintiffs' claims are barred, in whole or in part, because the product at issue was designed, manufactured, marketed and labeled with proper warnings, information, cautions and instructions, in accordance with the state of the art and the state of scientific and technological knowledge.

14. Plaintiffs' claims are barred, in whole or in part, because the labels and information accompanying the products at issue were approved by the U.S. Food and Drug Administration or other appropriate regulatory agencies.

15. Plaintiffs' claims are barred, in whole or in part, by applicable products liability statutes or other law providing absolute or limited immunity or a disputable presumption of immunity against liability for pharmaceutical products approved by the FDA. *See, e.g.*, N.J.S.A. § 2A:58C-4, -5.

16. Plaintiffs' claims are barred, in whole or in part, because the product at issue was not defective or unreasonably dangerous in that it complied with, at all relevant times, all applicable government safety standards.



17. Plaintiffs' claims are preempted, in whole or in part, by applicable federal law relating to the design, testing, producing, manufacturing, labeling, distributing, modeling, processing, and supply of Aredia<sup>®</sup> and/or Zometa<sup>®</sup>.

18. Plaintiffs' claims are barred, in whole or in part, because plaintiffs' injuries, if any, were the result of conduct of plaintiffs, independent third parties, and/or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening and superseding causes of the alleged injuries, including but not limited to plaintiffs' pre-existing medical conditions.

19. If plaintiffs suffered injury or damages as alleged, which is denied, such injury or damage resulted from acts or omissions of persons or entities for which NPC is neither liable nor responsible or resulted from diseases and/or causes that are not related to or connected with any product sold, distributed, or manufactured by NPC. Such acts or omissions on the part of others or diseases or causes constitute an independent, intervening and sole proximate cause of plaintiffs' alleged injury or damages.

20. Plaintiffs' claims are barred, in whole or in part, because plaintiffs' alleged injuries, if caused by Zometa<sup>®</sup>, which is denied, was the result of plaintiffs' own idiosyncratic reactions.

21. Plaintiffs failed to mitigate, which limits plaintiffs' damages, if any, in whole or in part.

22. Zometa<sup>®</sup> was fit and proper for its intended purposes and the social utility of the drug outweighed any possible risk inherent in the use of the product.

23. NPC has no legal relationship or privity with plaintiffs and owes no duty to plaintiffs by which liability could be attributed to it.

24. The claims of plaintiffs should be diminished in whole or in part in the amount paid to plaintiffs by any party or non-party with whom plaintiffs have settled or may settle.

25. Plaintiffs' claims are barred, reduced and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

26. NPC made no warranties of any kind, express or implied, or any representations of any nature whatsoever to plaintiffs. If any such warranties were made, whether express or implied, which NPC specifically denies, then plaintiffs did not rely on any such representations or warranties and/or failed to give notice of any breach thereof.

27. Notwithstanding the claims and contentions of plaintiffs, plaintiffs received all or substantially all of the benefit from the product that plaintiffs hoped and intended to receive, and, to that extent, any damages and/or restitution that plaintiffs might be entitled to recover from NPC must be correspondingly reduced.

28. Plaintiffs' causes of action are barred in whole or in part by plaintiffs' own contributory/comparative negligence.

29. Plaintiffs' recovery, if any, shall be reduced by those payments that plaintiffs receive from collateral sources.

30. If plaintiffs have been injured or damaged, no injury or damages being admitted, such injuries were not caused by an NPC product.

31. Plaintiffs' claims for punitive damages are barred because such an award would violate NPC's due process, equal protection and/or other rights under the United States Constitution, the New Jersey Constitution, the New York Constitution, the Virginia Constitution, and/or other applicable state constitutions.

32. Plaintiffs' claims for punitive damages are barred because plaintiffs have failed to allege conduct warranting imposition of punitive damages under New Jersey, New York, Virginia, and/or other applicable state laws.

33. Plaintiffs' claim for punitive damages is preempted, in whole or in part, by applicable federal law.

34. To the extent that New Jersey law applies to plaintiffs' claims, plaintiffs are limited in the amount, if any, plaintiffs may recover for punitive damages under N.J.S.A. § 2A:15-5.9 *et seq.*

35. To the extent that New Jersey law applies to plaintiffs' claims, plaintiffs are barred from recovering punitive damages under N.J.S.A. § 2A:58C-5(c) because Zometa<sup>®</sup> and Aredia<sup>®</sup> were subject to pre-market approval by the FDA, were approved by the FDA, and/or were generally recognized as safe and effective pursuant to regulations and conditions established by the FDA.

36. Punitive damages against NPC cannot be recovered based on alleged fraudulent representation to the FDA. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343 (2001); *see also* N.J.S.A. § 2A:58C-5(c); *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004); *McDarby v. Merck & Co., Inc.*, Nos. A-0076-07T1, A-0077-07T1, --- A.2d ---, 2008 WL 2199871, at \*41-45, (N.J. Super. A.D. May 29, 2008).

37. Plaintiffs' claims for punitive damages are barred in whole or in part because plaintiffs are not entitled to compensatory damages, no fault or other admissions being made.

38. Plaintiffs' fraud, misrepresentation, and suppression claims are preempted in whole or in part. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343 (2001); *Penn. Employees Benefit Trust Fund v. Zeneca Inc.*, 499 F.3d 239, 247 (3d Cir., 2007).

39. Plaintiffs' fraud, misrepresentation, and suppression claims are barred by plaintiffs' failure to plead them with reasonable particularity as required by Rule 9(b) of the Federal Rules of Civil Procedure.

40. Plaintiffs' fraud, misrepresentation, and suppression claims are barred by plaintiffs' failure to allege an "ascertainable loss." *See, e.g.*, N.J.S.A. § 56:8 *et seq.*

41. Any liability that might otherwise be imposed upon NPC is subject to reduction by the application of the doctrine of comparative fault and/or comparative negligence and/or contributory negligence.

42. NPC is not jointly and severally liable for any damages recoverable to the extent that such damages result from the conduct of parties other than NPC, no fault, damages, or other admissions being made.

43. Plaintiffs' claims are barred to the extent that plaintiffs seek relief under laws of states that do not govern plaintiffs' claims.

44. To the extent that Virginia law applies, plaintiffs' claims for strict liability are barred under Virginia law. *See e.g. Harris v. T.I., Inc.*, 243 Va. 63, 413 S.E. 2d 605 (1992); *Sensenbrenner v. Rust, Orling & Neale Architects, Inc.*, 236 Va. 419, 374 S.E. 2d 55 (1988).

45. To the extent that New Jersey law applies, plaintiffs' claims are subsumed and/or barred by the New Jersey Products Liability Act, in whole or in part. *See Sinclair v. Merck & Co., Inc.*, 195 N.J. 51, 54-55, 948 A.2d 587, 589 (N.J. 2008); *In re Lead Paint Litig.*, 191 N.J. 405, 436-37, 924 A.2d 484, 503-04 (N.J. 2007); *Brown ex rel. Brown v. Philip Morris, Inc.*, 228 F. Supp. 2d 506, 515-18 (D.N.J. 2002).

46. NPC hereby gives notice that it intends to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserves its right to amend this Answer to assert such defenses.

WHEREFORE, Defendant NPC demands judgment in its favor and against plaintiffs, dismissing plaintiffs' Complaint with prejudice, together with the costs of suit and such other relief as the Court deems equitable and just.

**JURY DEMAND**

Defendant Novartis Pharmaceuticals Corporation demands a jury trial as to all issues so triable.

Dated: August 11, 2008

Respectfully submitted,

s/ Ethan D. Stein  
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**CERTIFICATE OF SERVICE**

I hereby certify that on August 11, 2008, the Answer and Defenses of Defendant Novartis Pharmaceuticals Corporation to Plaintiffs' Complaint was filed with the Clerk of the Court and served in accordance with the Southern District's Rules on Electronic Service upon the following parties and participants:

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